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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,163	08/08/2003	Ralph Scannell	98-710-E	2945

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT PAPER NUMBER

1616

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/637,163

Applicant(s)

SCANNELL ET AL.

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-16, 19-27, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) 17, 18, 28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29,30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing instant compounds for treating histamine induced bronchoconstriction and related conditions, does not reasonably provide enablement for using instant compounds for treating all conditions in claims 29 and 30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Many of these conditions are unrelated to conditions that would be associated with bronchoconstriction, e.g. scombroid poisoning and psoriasis to name a couple. For this reason, one having ordinary skill in art would be required to do extensive experimentation to determine which condition would be treatable using instant compounds. The predictability in this art is high since the many of the diseases are unrelated and the mechanism of action of treating one condition may be totally different from the mechanism of action of treating an unrelated disease. Thus, one of ordinary skill in the art would not know based on the specification which compound would be effective at treating which condition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16,19-27,29,30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No: 6894059. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of non-identical scope. Note that USPN '059 claims 1,2,10,11 discloses compounds / compositions where G-G' is CHCH or C=C, whereas, instant claims 1,4,27,29,30 discloses compounds / compositions where G-G' is CHN, C=C, or CHCH. Note that claims 1,2,10,11 of USPN '059 anticipates claims 1,4,27,29,30 of USAN '163 since the claims in both documents disclose that G-G' is CHCH or C=C and that the compounds can be administered to patient suffering from asthma. Note that claims 3-4 of USPN '059 makes obvious the compounds of instant claims 2,5-16,19-26. The claims of the patent differ from the claims in the application in that patented claims specify compounds having a triple bond

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in Y whereas instant application defines Y as alkylene, alkenylene or alkynylene which includes that triple bond moiety (alkynylene) as Y. Thus, the patent makes obvious the instant invention. One would have been motivated at the time of instant invention to choose alkynylene since USPN '059 discloses specific compounds having Y as alkynylene.

Claims 1-3,5,7,9,11,13,15,19-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6451801. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of non-identical scope. Note that USPN '801 claims 1-5,21 discloses compounds / compositions where G-G' is CHN, whereas, instant claims 1-3,5,19,20,22-27 discloses compounds / compositions where G-G' is CHN, C=C, or CHCH. Note that claims 1-5,21 of USPN '801 anticipates claims 1-3,5,19,20,22-27 of USAN '163 since the claims in both documents disclose that G-G' is CHCN. Note that claims 6-22 of USPN '801 makes obvious the instant compounds of claims 7,9,11,13,15,21. The claims of the patent differ from the claims in the specification in that patented claims specify compounds having CHN as G-G' and optionally a triple bond in Y, whereas instant application defines Y as alkylene, alkenylene or alkynylene which includes that triple bond moiety as Y. Thus, the patent makes obvious the instant invention. One would have been motivated at the time of instant invention to choose G-G' as CHN and optionally alkynylene as Y since USPN '059 discloses specific compounds having G-G' as CHN and Y as alkynylene.

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Claims 1 and 2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 27 of U.S. Patent No. 6797713. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of non-identical scope. Note that USPN '713 makes obvious the compositions of the instant claims 1 and 27. USPN '713 claims specific composition comprising compounds which are species within the genus of compounds instantly claimed. Note that when instant composition comprises a compound where G-G' is CHN; R1,R2,X' = H; X = 4-chloro; Y = alkylene-O-substituted arene-alkynylene; W = N(OH)C(O)NH2, USPN '713 makes obvious the instant composition.

Claim Objection

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose instant compounds being employed in a method of inhibiting leukotriene- and histamine-mediated biological processes.

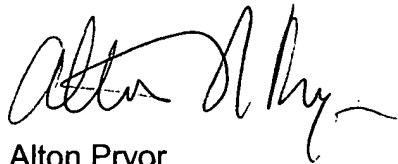
Claims 17 and 18 are objected to for being incomplete. The claims refer to compounds by number. One would have to look to the body of the specification in order to find the compound structure. This is improper. Note a claim must stand on its own.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alton Pryor
Primary Examiner
AU 1616